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In the Supreme Court of the United States

October Term, 1995

EDWARD A. FEAVER, acting secretary of the Florida Department of Health and Rehabilitative Services, et al.,

Petitioners

v.

ESTATE OF MARY DORIS LECLAIR, et al.,

Respondents

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF OF PETITIONERS

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QUESTION PRESENTED

Whether Article III of the U.S. Constitution places limits on the nature and scope of the remedies that a federal court is authorized to approve and enforce through a consent decree.

PARTIES TO THE PROCEEDINGS

The petitioner named in the caption is added pursuant to Rule 25(d)(1) of the Federal Rules of Civil Procedure. Mr. Feaver is the acting secretary of the Florida Department of Health and Rehabilitative Services (HRS). A second petitioner added under Rule 25(d)(1) is Calvin Ross, secretary of the Florida Department of Juvenile Justice. Mr. Ross is added as a party because he is responsible for facilities affected by the consent decree at issue.[1] Defendants in the trial court, and petitioners in this court, are Charles M. Kimber, Alvin Taylor, James Wilkins Jr., Charles Williams, and Lorraine Folkerts.

The respondents, who are the plaintiffs, are the Estate of Mary Doris LeClair, Alfred LeClair and Stella LeClair.

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[1] The consent decree presently affects 12 state facilities. They fall into three main categories: 1) for those with mental illness, 2) those with developmental disabilities and 3) juvenile delinquents. HRS operated juvenile facilities until 1994, when the Florida Legislature created the Department of Juvenile Justice.

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v.

ESTATE OF MARY DORIS LECLAIR, et al.,

Respondents

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

Edward Feaver and others petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit.

OPINIONS BELOW

Neither the court of appeals' nor the district court's opinions are published. The court of appeals' opinion is reproduced in Appendix A. The district court's opinion is reproduced in Appendix B.

JURISDICTION

The court of appeals entered its judgment on May 24, 1995. This Court's jurisdiction is invoked under 28 U.S.C. s. 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

Article III of the U.S. Constitution states in part:

> SECTION 2. The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made or which shall be made, under their Authority . . . to Controversies to which the United States shall be a Party; — to Controversies between two or more States; — between a State and Citizens of another State; — between citizens of different States; — between Citizens of the Same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

STATEMENT OF THE CASE

This case did not begin as an institutional reform action. It began as a lawsuit for compensatory and punitive damages for the wrongful death of Mary LeClair and accompanying civil rights violations. The second amended complaint (the last of three) alleged that Ms. LeClair, a young woman with developmental disabilities, died in 1979 as the result of an overdose of lithium during a clinical experiment in which she was an involuntary participant. App. C-8. At the time of her death, Ms. LeClair lived at a state facility for the developmentally disabled in Gainesville, Florida, then known as the Gainesville Sunland Training Center. App. C-4, 7. Lithium is a powerful psychotropic medication normally given as a treatment for some mental illnesses. App. C-9. According to the second amended complaint, prescribing lithium for Ms. LeClair was inappropriate. App. C-10. The second amended complaint also alleged that, once having prescribed lithium, the defendants failed to properly monitor Ms. LeClair's condition, which led to her death. App. C-11, 14-15. The plaintiffs are her estate and her parents.

In October 1983, the parties reached a settlement agreement. App. D. The agreement contained three features that are significant here. The first provided for the payment of compensatory damages and attorneys' fees. App. D-3. The second contained the plaintiffs' announcement that their litigation objective had been to change the manner in which the defendants administered psychotropic drugs. App. D-2. The third required the defendants to amend their highly detailed medical protocol for the administration of psychotropics along lines the plaintiffs found agreeable, and to implement those changes not only at Gainesville Sunland, but at all HRS facilities — including those for the developmentally disabled *and* those for the mentally ill and for juvenile delinquents. In addition, the amended protocol regulated the delivery of *all* psychotropics in *all* circumstances. App. D-3 and 5 et seq. The agreement also stated that the plaintiffs had exchanged their punitive damages claim for the agreement to amend and to implement the protocol. App. D-2. The district court adopted the agreement as a consent decree the day after the parties filed the settlement document. App. B-2. The decree was intended to last only nine months, but has been repeatedly extended because the defendants have not been able to comply fully with it at all their institutions and facilities.

In 1994, the defendants moved to vacate the decree on two grounds: First, the court lacked Article III jurisdiction to enforce an injunctive remedy because the plaintiffs lacked standing to secure injunctive relief in the first instance. Specifically, the defendants argued that imposition of injunctive relief provided the plaintiffs with no meaningful remedy for any tangible injury or risk of injury, since Ms. LeClair had died and her parents asserted no risk of future injury at the hands of the defendants. Second, the defendants argued that the district court lacked Article III jurisdiction because the relief in the decree addressed matters beyond the general scope of the case as set out in the pleadings. In particular, the defendants asserted, the decree regulates the

administration of all psychotropic drugs, not just lithium, at *all* HRS facilities, including those accommodating people with mental illness and juvenile delinquents, in *all* circumstances, not just clinical experiments.

Concerning the "standing" argument, the district court construed the defendants' position to be that the relief afforded must have been "specifically sought in the complaint and be providable by the Court." App. B-5-6. If this was true, the district court said, the holding in *Local Number 93, International Association of Firefighters, AFL-CIO v. City of Cleveland*, 478 U.S. 501 (1986), that in a consent decree the court can impose remedies broader than it could after a trial would be "superfluous." App. B-6.

Concerning the defendants' "general scope" argument, the district court held that *Local 93* required "a rational connection between the case and the relief." App. B-6. The district court recognized that limitations on a federal court's power to approve a consent decree implicated the "order" aspect of consent decrees, as opposed to their contractual side, and were necessary to prevent the purchase of injunctions by the parties. App. B-5. Moreover, the district court acknowledged that the "complaint concerned only a single instance of improper administration of a psychotropic medication, yet the consent decree imposed systemwide relief," and that the plaintiffs sought damages rather than injunctive relief. App. B-2. However, the court gave the second amended complaint a broad reading, concluding that the relief in the decree fell within the general scope of the case. From the presence of the punitive damages claim, which the plaintiffs exchanged for implementation of the amended psychotropic drug protocol, the court reasoned that the plaintiffs' prime litigation objective was to ensure that the defendants properly administered psychotropic medication to others. App. B-6. In the district court's view the plaintiffs' subjective intention, embodied in the claim for punitive damages, and their exchange of that claim for amendments to and implementation of a detailed

psychotropic drug protocol brought the provisions in the decree within the scope of the pleadings. App. B-6. However, the district court did not address the fact that the decree regulates the administration of *all* psychotropic drugs (not just lithium) at *all* institutions under HRS supervision, including those for the mentally ill and juveniles delinquents, in *all* circumstances, and not merely during clinical experime .ts.

The Eleventh Circuit Court of Appeals affirmed without opinion. App. A.

REASONS FOR GRANTING THE WRIT

I. THE DECISIONS OF THE COURTS BELOW CONFLICT WITH PRINCIPLES OF FEDERAL JURISDICTION AND FEDERAL REMEDIAL POWER ENUNCIATED BY THIS COURT AND BY THE COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA.

This case presents the Court for the second time with the question of how far a district court can go in approving and enforcing a consent decree. In this case, the district court's decision conflicts with principles embodied in precedent from this Court in two ways. First, the district court approved and has enforced a consent decree providing for relief that does not directly address or relate to the allegations of injury set out in the complaint. Thus, the remedy imposed falls outside the general scope of the case as made out by the pleadings. Second, the injunction in the consent decree is not remedial, as this Court has defined the term, because it is not designed to restore the plaintiffs to the position they would have occupied absent the defendants' conduct, or to protect them from the unreasonable risk of future injury.

A. THE LOWER COURTS' DECISIONS CONFLICT WITH *LOCAL 93, INTERNATIONAL ASSOCIATION OF*

FIREFIGHTERS, AFL-CIO v. CITY OF CLEVELAND.

This Court has said that the relief in a consent decree must fall within the general scope of the case as made out in the pleadings. *Local Number 93, International Association of Firefighters, AFL-CIO v. City of Cleveland*, 478 U.S. 501, 525, 106 S.Ct. 3063, 3077, 92 L.Ed.2d 405 (1986). The lower courts' decisions violate this principle and are at odds with the broader analysis employed in *Local 93*.

In *Local 93*, a union appealed the district court's approval of a consent decree in a Title VII job discrimination case that provided for race-conscious hiring and promotional criteria. The union argued that the court was not empowered under the statute to approve the decree in part because a common-law of consent decrees barred the entry and enforcement of the decree's remedies.

This Court recognized that there were general limits on the district court's ability to approve and to enforce the decree:

> To be sure, a federal court is more than a "mere recorder of contracts" from whom parties can purchase injunctions; it is "an organ of government constituted to make judicial decisions . . ." . . .

Id., 478 U.S. at 525

The Court then outlined three criteria for determining when a district court had exceeded its authority:

1. A consent decree must "spring from and serve to resolve a dispute within the court's subject-matter jurisdiction";

2. Consistent with this requirement, the consent decree must come "'within the general scope of the case made by the pleadings'"; and

3. The decree "must further the objectives of the law upon which the complaint was based."

Id.

The Court did not describe in detail what it meant by "the general scope of the case made by the pleadings" because this was not an issue in the case. However, the Court said that because the "parties' consent animates the legal force of a consent decree . . . a federal court is not necessarily barred from entering a consent decree because the decree provides broader relief than the court could have awarded after a trial." *Id.*

This notion that a court can impose a broader remedy by consent than it could after trial has confused the lower courts. They have lost sight of the fact that there are two types of remedial overbreadth. The first deals with how appropriately the remedy is targeted, how directly it addresses and relates to the matters proven or raised in the complaint. A remedy is overbroad here if it addresses a matter either not proven or not raised in the complaint.[2] *See point I(B) below.* The second type of overbreadth deals with the question of how broadly the remedy may sweep when it directly addresses matters raised in the pleadings.[3]

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[2] For example, a prison institutional reform consent decree illustrates this type of overbreadth when the complaint raised inadequate medical care and the decree contains provisions concerning fire safety.

[3] An example of the second type of overbreadth would occur in a consent decree case involving a challenge to prison medical care in which defendant-prison officials agreed to

This second type of overbreadth was at issue in *Local 93*. The scope of the case was the elimination of job discrimination, and the remedy in the decree directly related to the allegations of unequal treatment. Thus, in *Local 93*, the Court was presented with the question whether the injunctive remedy was invalid because it provided for greater, appropriately targeted relief than the Court, by law, could grant after a trial.

In the situation presented in *Local 93*, the Court said one must look to the purpose behind the purported restriction on the federal court's authority to enter and to enforce the decree to determine the validity of the remedy. If the purpose behind the restriction is not "implicated by voluntary agreements," the federal court can approve and enforce the decree. *Id.*, at 3078.

The circumstances of the present case differ from those in *Local 93* because the consent decree's remedy is not appropriately targeted. Even so, the district court's decision conflicts with the principle enunciated in *Local 93* that the restriction should not implicate the purpose behind the restriction on federal remedial power.

In *Local 93*, this Court directed the lower courts to determine whether the judicial limitation at issue is "implicated" by the breadth of the remedy. In the present case, the decree's remedies implicate Article III's case-or-controversy requirement, the applicable limitation on federal remedial power.

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incorporate state law, agency policies or standards such as those adopted by organizations like the American Correctional Association concerning medical care in the decree to be enforced by an injunctive order. It is doubtful that a federal court would have the power to require compliance with these provisions after trial without the defendants' consent. *See e.g., Pennhurst State School & Hospital v. Halderman*, 465 U.S. 89, 104 S.Ct. 900, 79 L.Ed.2d 67 (1984).

Article III's case-or-controversy requirement fundamentally limits federal remedial power. *Warth v. Seldin*, 422 U.S. 490, 498-499, 95 S.Ct. 2197, 2205, 45 L.Ed.2d 343 (1975). Absent an allegation of actual harm, the exercise of federal judicial power to provide a remedy "would be gratuitous and thus inconsistent with the Art. III limitation." *Simon v. Eastern Kentucky Welfare Rights Organization*, 426 U.S. 26, 38, 96 S.Ct. 1917, 1924, 48 L.Ed.2d 450 (1976); *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99, 99 S.Ct. 1601, 1608, 60 L.Ed.2d 66 (1979).

In *Valley Forge Christian College v. Americans United for Separation of Church and State*, 454 U.S. 464, 102 S.Ct. 752, 70 L.Ed.2d 700 (1982), the Court identified other significant purposes behind Article III's limitation. The Court said that the "power to declare rights of individuals and to measure the authority of governments . . . 'is legitimate only in the last resort, and as a necessity in the determination of real, earnest and vital controversy.'" *Id.*, 454 U.S. at 471. Otherwise, the power is "'not judicial' . . . in the sense in which judicial power is granted by the Constitution to the courts of the United States.'" *Id.* The requirement that federal judicial power be exercised only upon the allegation of an injury in fact was essential to "limit the federal judicial power 'to those disputes which confine federal courts to a role consistent with a system of separated powers and which are traditionally thought to be capable of resolution through the judicial process.'" *Id.*, 454 U.S. at 472.

The *Valley Forge* Court then identified three "'implicit policies embodied in Article III.'" First, the Article "tends to assure that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action." *Id.* Second, the Article assures a factual setting in which the litigant asserts a claim of injury in fact so that the court can act on the issues with some

confidence that its order will not "pave the way for lawsuits which have some, but not all, of the facts of the case actually before the court." *Id.* Finally, Article III's restrictions reflect "a due regard for the autonomy of those persons likely to be most directly affected by a judicial order. The federal courts have abjured appeals to their authority which would convert the judicial process into 'no more than a vehicle for the vindication of the value interests of concerned bystanders.'" *Id.*

Because of the concern that federal courts may be pressed into issuing gratuitous remedies vindicating mere value interests, parties are prohibited from consenting to Article III jurisdiction. *See, e.g., FW/PBS v. City of Dallas*, 493 U.S. 215, 231, 110 S.Ct. 596, 607, 107 L.Ed.2d 603 (1990) ("[E]very federal appellate court has a special obligation to 'satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review,' even though the parties are prepared to concede it.").

Holding otherwise permits parties to present "'generalized grievance[s]'" and "abstract questions" to the court. *Warth v. Seldin*, 422 U.S. at 499-500.

Therefore, Article III is directly implicated by a consent decree that provides remedies for injuries not alleged in the complaint. By providing for such remedies in a consent decree, the parties have expanded the court's Article III jurisdiction by consent; they have provoked the court into entering a remedial order that is gratuitous; they have presented generalized grievances and abstract questions directed to mere value interests to the court; and they have pressed the court "to declare rights of individuals and to measure the authority of governments" on matters in which no injury in fact has been alleged and the matters at issue are not concrete. Thus, under *Local 93*, the injunction requiring the adoption and implementation of a detailed medical protocol is invalid.

B. THE LOWER COURTS' DECISIONS CONFLICT WITH *MISSOURI v. JENKINS*.

Under *Missouri v. Jenkins*, — U.S. —, 115 S.Ct. 2038 (1995), there is a clear Article III basis for the requirement that the remedies in a consent decree must fall within the general scope of the case as set out in the pleadings. While the Court did not define "general scope" in *Local 93*, Article III's injury-in-fact requirement provides a clear, objective boundary to the scope of any case.

Last term in *Missouri v. Jenkins*, this Court held that a federal remedial decree in a school desegregation case exceeded the scope of the district court's remedial powers. The *Jenkins* majority identified three factors that constrained federal courts:

- The nature and scope of such remedies must directly address and relate to the violation alleged in the complaint to offend the Constitution.

- The remedy "must be remedial in nature, that is, it must be designed as nearly as possible 'to restore the victims of [federal law violations] to the position they would have occupied in the absence of such conduct.'"

- "[T]he federal court devising a remedy must take into account the interests of state and local authorities in managing their own affairs, consistent with the Constitution."

Id., 115 S.Ct. at 2049. The majority did not identify the specific source of these limitations. However, Justices

O'Connor and Thomas found the source in Article III of the U.S. Constitution. *Id.*, at 2061 and 2071.[4]

Thus, whatever the source, there are *fundamental* limitations on federal remedial power. If the limitations are fundamental, they must apply in all circumstances, including when the district court adopts and enforces a consent decree.[5] This explains the Court's instruction in *Local 93* that consent decree provisions must fall within the general scope of the case as made in the pleadings. The reason for the "general scope" limitation is obvious: Because the parties often enter consent decrees to avoid trial, the court is deprived of a judgment on which to base its decree. *See, e.g., Badgley v. Varelas*, 729 F.2d 894, 899 (2d Cir. 1984). Without a judicial finding of federal violations to guide the court in the exercise of its injunctive power, the court must fall back on the pleadings to define the limits of its remedial authority.

The issue then becomes what in the pleadings provides concrete guidelines to the scope of the case, and thus, the scope of the court's remedial power in approving consensual relief. Consistent with Article III's requirement that the court's authority extends only to cases or controversies, the court must look to the allegations of injury in fact. These are the matters the plaintiff chose to put at issue in the case.

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[4] Justice O'Connor identified specific *jurisdictional* limitations arising under Article III. *Id.*, at 2061. ("The necessary restrictions on our jurisdiction and authority contained in Article III of the Constitution limit the judiciary's institutional capacity to prescribe palliatives for societal ills.") Justice Thomas focused on comity and separation of powers concerns. *Id.*, at 2070-2071.

[5] *Jenkins* was a litigated case; that is, a case tried to judgment.

As this Court said in *Freeman v. Pitts*, 503 U.S. 467, 112 S.Ct. 1430, 1445, 118 L.Ed.2d 108 (1992):

> The authority of the district court [in institutional reform cases] is invoked at the outset to remedy particular constitutional violations. In construing the remedial authority of the district courts, we have been guided by the principles that "judicial powers may be exercised only on the basis of a constitutional violation," and that the "nature of the violation determines the scope of the remedy." . . . A remedy is justifiable only insofar as it advances the ultimate objective of alleviating the *initial constitutional violation*. [emphasis added]
>
> We have said that the court's end purpose must be to remedy the violation and in addition to restore state and local authorities to the control of a school system that is operating in compliance with the constitution.

Since *Freeman* was a consent decree case, this Court must have meant the *injury alleged* when it spoke of the "initial constitutional violation."

To summarize, under *Missouri v. Jenkins*, Article III limits the scope of federal remedial power to the harm proven. In a consent decree case, lacking a judicial determination of violations of federal law, Article III limits the scope of federal remedial power to the injury alleged.

In the present case, the district court deviated from this Court's precedent in three significant ways. First, it found that *Local 93* only required a "rational connection between the case and the relief." App. B-6. This is a far more lenient standard than "directly address and relate," the Article III requirement under *Jenkins*. Second, the district court improperly relied on the plaintiffs' subjective intentions to define the scope of the case. Fidelity to the spirit of Article III, *Local 93*, and *Jenkins* requires that

the relief in the consent decree must directly address and relate to the allegations of injury in fact. Reliance on the plaintiffs' subjective intentions to reform HRS's procedures for administering psychotropic drugs resulted in gratuitous remedies vindicating mere value interests of bystanders in violation of *Simon v. Eastern Kentucky Welfare Rights Organization, supra,* and *Valley Forge Christian College v. Americans United for Separation of Church and State, supra.* Third, the remedial injunction in the decree is not "designed as nearly as possible 'to restore the victims of [federal law violations] to the position they would have occupied in the absence of such conduct,'" as required by *Jenkins.*

Permitting the district court, in a consent decree case, to approve unrelated relief such as that at issue here is tantamount to permitting the expansion of the court's jurisdiction by agreement – in effect, the purchasing of an injunction from the district court.

C. THE LOWER COURTS' DECISIONS CONFLICT WITH THOSE OF OTHER CIRCUIT COURTS.

The Circuit Court of Appeals for the District of Columbia touched on the question whether a district court could require consensual relief that addressed matters not raised in the complaint in *U.S. v. Microsoft,* 56 F.3d 1448, 1995 WL 357850 (D.C. Cir. June 16, 1995). In *Microsoft,* the district judge refused to approve an antitrust consent decree because, in his view, the decree should have addressed matters not raised in the complaint. The circuit court reversed and remanded with instructions to enter the decree, disapproving the district court's insistence that the decree provide remedies for matters not alleged. *Id.,* 1995 WL at 11 ("since the claim is not made, a remedy directed to that claim is hardly appropriate"). See also *Phoenix Resources Inc. v. Duncan Township,* 155 F.R.D. 507, 509 (M.D. Penn. 1994) (district court refused to approve a consent decree in part because provisions addressed

disputes not raised in the complaint); and *Beth V. v. Carroll*, 155 F.R.D. 529, 533 (E.D. Pa. 1994).[6]

Because the remedies in the present consent decree are "directed to a claim not made," the district court's decision conflicts with the principle enunciated in *U.S. v. Microsoft.*

II. WHETHER ARTICLE III AUTHORIZES FEDERAL COURTS TO ENFORCE CONSENSUAL RELIEF THAT DOES NOT DIRECTLY ADDRESS INJURIES ALLEGED IN THE COMPLAINT IS A MATTER OF GREAT PUBLIC IMPORTANCE.

Federal courts view consent decrees as important tools to resolve litigation, especially institutional reform litigation.[7] However, the nation's historical experience with consent decrees in such litigation has uncovered serious potentials for abuse. If a decree's provisions are not

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[6] "A number of legal scholars and judges have cautioned that the lack of clear guidelines for the drafting and implementation of [institutional reform] consent decrees, combined with the broad discretion vested in federal district courts, raise questions about the legitimacy of judicial involvement in this process. I believe that those questions are not motivated by opposition to the substantive results of the litigation or to the use of the federal courts as a vehicle for social and economic reform, but stem from a genuine concern and respect for the court, and from the *command of the "case or controversy" limitation on federal judicial power contained in Article III of the United States Constitution*. . . . As a federal judge, I have an enormous responsibility, *consistent with Article III*, to use my office well, and consistent with my duty to interpret and enforce the laws, to do good." [emphasis added]

[7] *See e.g., Cotton v. Hinton*, 559 F.2d 1326, 1331 (5th Cir. 1977) (in a case involving settlement by consent decree, the court observed that "settlements contribute greatly to the efficient utilization of our scarce judicial resources.").

targeted to relieving injuries alleged in the complaint, a federal court will often find itself enforcing remedies that entangle it deeply in state affairs on matters that are not issues of federal concern, but rather are issues of state law and public policy.

As Justice Thomas has written, "I believe that we must impose more precise standards and guidelines on the federal equitable power, not only to restore predictability to the law and reduce judicial discretion, but also to ensure that constitutional remedies are actually targeted toward those who have been injured." *Missouri v. Jenkins*, 115 S.Ct. at 2071. Determining these precise standards is a matter of great public importance for the states and for the country's citizens.

District Judge Anita Brody discussed the dangers inherent in the use of consent decrees in her thoughtful opinion in *Beth V. v. Carroll*, 155 F.R.D. at 531-532. Institutional reform consent decrees often come with a price tag attached to secure the reforms — a price that is often considerable. In the past, the courts have assumed that the normal adversary process will ensure proper checks on the scope of such a decree, leaving it within the realm of what the defendant can and is willing to pay for. However, Judge Brody found that there are two instances where this check does not operate. One significant danger Judge Brody identified was that

> a defendant department sees a lawsuit as "an opportunity for it to secure more funds than it might otherwise receive in the budget derby and therefore look[s] on the suit as a friendly one". . . There are many examples of such "sweetheart suits", most of which did not begin as outright collusion, but nonetheless end with the parties drawing up a "wish list" for the court to approve and the state to finance.

Id., 155 F.R.D. at 532.

Judge Brody also saw another danger:

> Another instance in which the government as a party may not provide the expected check on the scope and cost of a negotiated remedy is when an outgoing administration negotiates a consent decree that it will not have to abide by.

Id.

In these passages, Judge Brody has identified threats to the democratic process. Ordinarily, state legislatures are responsible for making the hard choices of what social programs to fund from limited resources. She saw the possibility that executive branch officials would circumvent their legislatures by working with plaintiffs in federal institutional reform litigation to create "wish lists" addressing a range of issues beyond those raised in the complaint or unnecessary to cure constitutional violations. The parties would incorporate these "wish lists" into a consent decree, enforceable as a judicial order, and the defendant-officials would use the decree to secure funding that the legislature will not appropriate.

Judge Brody is not alone in recognizing these significant threats. Others also have seen that institutional reform litigation often presents program administrators with a temptation they can't refuse — a way to leverage appropriations from a state legislature for pet programs. See Levine, *The Role of Special Master in Institutional Reform Litigation: A Case Study*, 8 Law & Policy 275 (1986). The article is a case study of litigation to reform Maine's mental health treatment system. One defendant, the administrator of the mental health facility that was the focus of the litigation, quickly realized how he could use the litigation to pry funds from the legislature: "Zitnay, an experienced and gifted institutional administrator, immediately recognized the opportunity the suit presented to gain resources and leverage to improve Pineland." *Id.*, at 279. Zitnay also told the writer "that

they might be able to use the consent decree to promote programs they wanted in ways they might not otherwise be able to do." *Id.*, at 281. Maine's attorney general, not a party at the time, approved the agreement apparently without being told how administrators like Zitnay intended to use it. The attorney general found out to his chagrin when he became governor and a defendant in the case. "[O]ne of the main reasons for the split between Zitnay and Brennen was the Governor's realization that the decree had been intended to gain leverage over the Governor's discretion in the budget process." *Id.*, at 285. See also Esterbrook, *Justice and Contract in Consent Judgments*, 1987 U.Chi. Legal Forum 19, 34; Laycock, *Consent Decrees Without Consent: The Rights of Nonconsenting Third Parties*, 1987 U.Chi. Legal Forum 19, 74; Shane, *Federal Policy Making By Consent Decree: An Analysis of Agency and Judicial Discretion*, 1987 U.Chi. Legal Forum 19, 273; McConnell, *Why Hold Elections? Using Consent Decrees to Insulate Policies from Political Change*, 1987 U.Chi. Legal Forum 295.

Institutional reform litigation thus pits administrators grasping at any means to fund their programs against state legislatures. In short, some state officials are eager to enter collusive, broad consent decrees with plaintiffs to further their *personal* policy agendas. The court must consider this when adopting a decree. Otherwise, it may find itself a tool for those interested in matters far removed from the preservation of federal rights.

As the Seventh Circuit said in *Kasper v. Board of Elections Commissioners of the City of Chicago*, 814 F.2d 332, 340 (7th Cir. 1987), "district judges should be on the lookout for attempts to use consent decrees to make end runs around the legislature . . ." Furthermore, "[d]emocracy does not permit public officials to bind the polity forever . . . temporary officeholders may not contract away the basic powers of government . . . in the same way natural persons may make enduring promises about their

own future behavior." *Evans v. City of Chicago*, 10 F.3d 474, 478 (7th Cir. 1993).[8]

The failure to guard against these threats results in significant, unwarranted federal judicial intrusion into state affairs on matters not relevant to the prevention and remediation of violations of federal law. See *Id.*, at 479 ("courts are bound by principles of federalism (and by fundamental differences between judicial and political branches of government) to preserve the maximum leeway for democratic governance."). Since broad consent decrees that provide remedies to injuries not alleged in the complaint undermine the democratic process, this Court should grant the writ.

In addition, authorizing the district courts to enforce consent decrees that provide for remedies that do not directly address and relate to injuries alleged in the complaint will discourage the use of consent decrees in

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[8] *Evans* dealt with restrictions on a city's ability to enact budgets and fix appropriations — fundamental aspects of state sovereignty. Our case, of course, is somewhat different. It involves restrictions on the judgment of government clinicians in the way they administer medications. The protocols entombed in the regulation, 95-3, represent the plaintiffs' and the defendants' notions of good practice — as they stood in 1983. But ideas about what is good practice do not remain constant. Community medical standards change over time. However, Florida's ability to adapt to changing ideas of good practice is hostage to the plaintiffs' and court's approval. Changes to the regulation require the parties to seek modification under the standards of *Rufo v. Inmates of Suffolk County*, 502 U.S. 367, 112 S.Ct. 748, 116 L.Ed.2d 867 (1992). This court has discouraged federal judicial interference in matters of clinical judgment because courts are not equipped to make those decisions. *See e.g., Youngberg v. Romeo*, 457 U.S. 307, 102 S.Ct. 2452, 73 L.Ed.2d 28 (1982)

settling litigation. Concern about the abuse of consent decrees to leverage appropriations by overly broad or detailed provisions actually discourages many state officials from approving the use of consent decrees to settle litigation. In Florida, for instance, the governor has directed that he will not approve any settlement in an institutional reform case that involves a consent decree. See brief of amici curiae State of Florida and others in *Rowland v. Juan F.*, U.S.S.Ct. docket number 94-1731, at 16.

If this Court wishes to preserve the consent decree as a tool to resolve litigation, it must provide clear instructions on the scope of a district court's Article III powers to enforce consensual relief.

III. AS AN ALTERNATIVE TO GRANTING THE WRIT, THIS COURT SHOULD VACATE THE OPINIONS BELOW AND REMAND WITH INSTRUCTIONS TO RECONSIDER IN LIGHT OF *MISSOURI v. JENKINS*.

As the Court pointed out in *Missouri v. Jenkins*, Article III limitations on the remedial power of federal courts are fundamental. If they are fundamental, they must apply in all situations, including the entry and enforcement of consent decrees. For, as this Court has said, a consent decree is "an agreement that the parties desire and expect will be reflected in and be enforceable as a judicial decree that is subject to the rules generally applicable to other judgments and decrees." *Rufo v. Inmates of Suffolk County*, 502 U.S. 367, 112 S.Ct. 748, 757 (1992).

Therefore, because Article III limitations are fundamental, and consent decrees are subject "to the rules generally applicable to other judgments and decrees," this Court should vacate the decisions below and remand for reconsideration in light of *Missouri v. Jenkins*.

CONCLUSION

In light of the foregoing, the petitioners ask the Court to grant the writ. In the alternative, the petitioners ask the Court to vacate the opinions below and remand with instructions to reconsider in light of *Missouri v. Jenkins*.

RESPECTFULLY SUBMITTED,

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Dated August 1995

APPENDIX A

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 94-3037

D.C. Docket No. GCA-81-0008-MMP

ESTATE OF MARY DORIS LECLAIR, by
its personal representative;
ALFRED LECLAIR, her parent;
STELLA LECLAIR, her parent,

Plaintiffs-appellees

v.

CHARLES A. WILLIAMS, DR., individually
and in his official capacity as Medical
Director of Sunland Training Center,
Gainesville, FL; JAMES L. WILKINS, JR.,
individually and in his official capacity
as Superintendent of Sunland Training Center,
Gainesville, FL; CHARLES M. KIMBER,
individually and in his official capacity as Director
of Developmental Services of the Dept.
of Health and Rehabilitative Services, State
of Florida; DAVID H. PINGREE, individually
and in his official capacity as former Secretary
of the Dept. of Health and Rehabilitative
Services, State of Florida; ALVIN J. TAYLOR;
LORRAINE FOLKERTS,

Defendants-appellants.

Appeal from the United States District Court
For the Northern District of Florida

(May 24, 1995)

Before HATCHETT and EDMONDSON, Circuit Judges, and GIBSON*, Senior Circuit Judge.

PER CURIAM:

Affirmed. See Eleventh Circuit Rule 36-1

*Honorable John R. Gibson, Senior U.S. Circuit Judge for the Eighth Circuit, sitting by designation.

APPENDIX B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
GAINESVILLE DIVISION

ESTATE OF MARY DORIS DIANE LECLAIR, et al.,
Plaintiffs,

v. Case No. GCA-81-0008-MMP

DR. CHARLES WILLIAMS,
et al.,

Defendants

_____/

ORDER

This case is before the court on the defendants' motion to vacate a consent decree entered into over 10 years ago. For the reasons discussed below, the motion is DENIED.

BACKGROUND

Mary LeClair was a resident of Gainesville Sunland, an institution for persons with developmental disabilities. While there she was given lithium carbonate, primarily for the purposes of experimentation. She died as a result of being given the medicine. Her parents brought suit on their own and her behalf, alleging that the administration of the medicine to her violated her federal statutory and constitutional rights. The plaintiffs sought compensatory and punitive damages from various officials, and their stated litigation objective was to ensure that proper procedures were implemented by the Florida Department of Health and Rehabilitative Services ("HRS") for the administration of psychotropic medications.

The parties offered a proposed settlement agreement on October 12, 1983, and the court approved it the next day. The consent decree called for, among other things, the implementation of a regulation by HRS, concerning psychotropic medication. The court retained jurisdiction to oversee compliance by the defendants. The oversight was supposed to last only 9 months but has lasted to this day because of the defendants' failure to comply with the consent decree in certain instances.

On February 17, 1994, the defendants moved to vacate the consent decree, arguing that it was void ab initio because (1) the plaintiffs lacked standing to confer jurisdiction on the court; and (2) the relief provided goes beyond the scope of the case as made by the pleadings.

DISCUSSION:

The complaint concerned only a single instance of improper administration of a psychotropic medication, yet the consent decree imposed systemwide relief. Also, the plaintiffs sought compensatory and punitive damages, but not injunctive relief. Yet the systemwide relief provided for in the consent decree was injunctive in nature. Despite these facts, and *Bobby M* notwithstanding, the consent decree was a valid exercise of the Court's equitable power.

Consent decrees are dual-natured, with attributes of both contracts and judicial decrees. This duality is inherent and inescapable. Thus, instead of attempting to categorize consent decrees as contracts *or* as judgments, courts have given consent decrees different treatment for different purposes.

For example, in *Local Number 93 v. City of Cleveland,* 106 S.Ct. 3063 (1986), the Court held that parties to a consent decree may agree to broader relief than the court could have imposed after trial. This is because, in that case, the obli-

gations of the consent decree derived primarily from the contractual aspects of a consent decree. Thus, the Court focused on the contractual aspect of the consent decree. However, the Court still noted that the contractual power of the parties was not untrammeled — the consent decree must bear some relation to the litigation. The consent decree must spring from and serve to resolve a dispute within the subject-matter jurisdiction of the court; the consent decree must come within the general scope of the case made by the pleadings; and the consent decree must further the objectives of the law upon which the complaint is based. These concerns involve the decretory nature of a consent decree and ensure that federal courts do not become mere "'recorder[s] of contracts' from whom parties can purchase injunctions."

In contrast, the *Bobby M* case focused on the decretory aspect of a consent decree after the defendants had attacked the contractual aspect. In that case, the defendants argued that the consent decree was not a valid contract because the defendants lacked the authority under the Florida Constitution and statutes to bind the legislature to expend funds. The relief agreed to by the defendants in *Bobby M,* system-wide reform of the juvenile justice, would have required the expenditure of vast funds by the legislature. Thus, the defendants argued that they lacked the authority to promise such relief. The defendants concluded that this required vacation of the consent decree.

This Court concluded otherwise. Even if the consent decree were technically invalid as a contract, the Court still retained equitable power to remedy violations of federal law. This Court stated, "a consent decree is enforceable notwithstanding conflicts with [a] state constitution, if the decree is required to alleviate violations of federal law." Thus, this Court held that the consent decree would not be completely vacated, even if it were not a valid contract.

This Court did limit the scope of the consent decree, however, because in *Bobby M* this Court was focusing on the decretory aspect of a consent decree. The limitation was due to the fact that the obligation in *Bobby M* arose from the equitable power of the court, not from the contractual rights of the parties. The court stated:

> Because the defendants lacked the authority to enter into such a consent decree under the Florida constitution, the consent decree would be unenforceable between the parties as a contract. The only way such a consent decree could be enforceable is if this Court had the power to fashion such a remedy after a trial on the merits.

Thus, the Court limited the obligatory reach of the consent decree to relief which pertained to the plaintiff's specific allegations of constitutional violations. "Just as the allegations of constitutional violations were confined to conditions existing at the training schools, so [too] the relief granted by the consent decree must be confined."

This Court brushed aside the plaintiffs' argument that the parties to a consent decree may agree to relief which is broader than that which the court might have imposed after trial. The court's reasoning was that, in *Bobby M,* the source of obligation was the Court's equitable powers, not the parties' contractual powers. Thus, the parties' right to agree to broader relief was not relevant. The court distinguished *Local Number 93,* noting that the Supreme Court had made it clear that, "although the parties may agree to broader relief in a consent decree, the consent decree will not be enforced if it is 'otherwise shown to be unlawful.'"

While at first blush it is tempting to place the case sub judice in the same analytical bin as *Bobby M,* that case actually dictates a different result. Looming large in *Bobby M* was the defendants' attack on the contractual aspect of the consent decree. The defendants argued that the "contract"

was invalid due to their alleged lack of authority to provide the relief they promised.

Because the consent decree was invalid as a contract, the Court could only enforce the consent decree within the confines of its equitable powers. Thus, the fact that the parties can agree to relief broader than what the court could impose after trial was irrelevant because, in essence, there was no agreement. Instead, the obligation arose from the Court's equitable powers, whose obligatory reach is less broad.

No such attack on the contractual aspect of the consent decree is made in this case. Instead, the defendants challenge only the Court's ability to enforce the contract. The defendants argue that the consent decree is invalid because the plaintiffs did not seek injunctive relief originally and the consent decree contained elements of injunctive relief. As a result, according to the defendants, the decree did not come within the general scope of the case made by the pleadings.

This case, therefore, is one in which the source of obligation is the contractual aspect of a consent decree. It is the parties' agreement which animates the consent decree, not merely the Court's equitable power. Thus, unlike in *Bobby M,* the parties in this case may agree to relief which is broader than the relief the Court might have fashioned after trial on the merits.

Local Number 93 provides additional limitations, however. The consent decree must spring from a dispute within the Court's subject matter jurisdiction and must come within the general scope of the pleadings. These exceptions cannot be considered as rapacious as defendants contend or they would swallow the rule from *Local Number 93.* The defendants contend that to be within the general scope of the pleadings requires that the remedy granted be specifi-

cally sought in the complaint and be providable by the Court. However, if the Court could enter the relief regardless of the parties agreement, the issue would not arise as to whether the relief provided in the consent decree goes beyond what might be granted after trial. Thus, the holding in *Local Number 93* — that the parties can agree to more than what the Court could impose after trial — would be superfluous.

Thus, the exceptions found in that case are intended insure a rational connection between the case and the relief. First, the subject matter requirement of *Local Number 93* merely requires that the dispute as originally pled be within the subject matter jurisdiction of the Court. In this case, the federal question presented makes the case fall squarely within the subject matter discretion of the Court. Second, the general scope of the case, as made by the pleadings, is improper administration of psychotropic drugs. The primary litigation objectives of the plaintiffs (as noted in the consent decree itself) was to prevent this from happening to someone else. The plaintiffs' initial method of ensuring this was to seek punitive damages. The plaintiffs, however, agreed to forego punitive damages based on the defendants' promise to meet the plaintiffs' litigation objective in a more straightforward way, implementing a regulation. It would fly in the face of common sense to ignore the fact that the general scope of the case was to prevent future improper administration of psychotropic drugs. The relief provided addressed exactly that concern and thus falls within the ambit of *Local Number 93.*

CONCLUSION:

The parties to a consent decree which is valid contractually may agree to relief which is greater than that the Court could have imposed after a trial on the merits. The consent decree must spring from a dispute within the Court's subject

matter jurisdiction and must come within the general scope of the case as made by the pleadings. Both of these requirements are met in this case. Therefore the consent decree was a valid exercise of this Court's equitable authority. Accordingly, it is hereby

ORDERED AND ADJUDGED:

1. The defendants' motion to vacate the consent decree is DENIED.

DONE AND ORDERED this 1st day of August, 1994.

/s/ Maurice M. Paul
MAURICE M. PAUL, CHIEF JUDGE

APPENDIX C

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
GAINESVILLE DIVISION

ESTATE OF MARY DORIS DIANE LECLAIR by its personal representative, ALFRED LECLAIR, and ALFRED AND STELLA LECLAIR, her parents,

Plaintiffs,

v.

DR. HARVEY R. LANGEE, individually and in his official capacity as Psychiatrist of Sunland Training Center, Gainesville, Florida

DR. CHARLES A. WILLIAMS, individually and in his official capacity as Medical Director of Sunland Training Center, Gainesville, Florida,

JAMES L. WILKINS, JR., individually and in his official capacity as Superintendent of Sunland Training Center, Gainesville, Florida,

CHARLES M. KIMBER, individually and in his official capacity as Director of Developmental Services of the Department of Health and Rehabilitative Services, State of Florida,

DAVID H. PINGREE, individually and in his official capacity as former Secretary of the Department of

Civil Action
No. GCA 81-0008

SECOND
AMENDED
COMPLAINT

Health and Rehabilitative Services,
State of Florida,

ALVIN J. TAYLOR, in his official
capacity as present Secretary of
the Department of Health and
Rehabilitative Services, State of Florida,

LORRAINE FOLKERTS, individually and
in her official capacity as Pharmacist
of the Sunland Training Center,
Gainesville, Florida, and

STATE OF FLORIDA,

Defendants.

INTRODUCTORY STATEMENT

1. This complaint arises out of the wrongful death of Mary LeClair, a blind and profoundly retarded ward of the Florida Department of Health and Rehabilitative Services who was involuntarily committed to the care of the defendants at the Sunland Training Center in Gainesville. Mary's death was caused by the failure of the defendants acting under color of state law to fulfill their federal statutory and constitutional duties and analogous duties under state law to provide Mary with a safe, humane and habilitative environment. Specifically, the defendants denied Mary her right to habilitation in the least restrictive setting by unnecessarily administering a potentially lethal experimental drug to her in an open clinical trial without her knowledge or consent or that of her parents. In addition, the defendants denied Mary her right to life and her right to be free from harm by failing to design and implement proper safeguards for the administration of the test drug. And further, the

defendants denied Mary her right to have a research protocol filed and approved to assure her suitability, consent and safety as a subject of institutional experimentation. On behalf of her estate and themselves, Mary's parents seek compensatory and punitive damages and a declaratory judgment that the defendants' actions and omissions violated fundamental constitutional and statutory rights.

JURISDICTION

2. This action arises under 42 U.S.C. § 1983 for deprivation under color of state law of rights secured to the plaintiff by the First, Eighth, Ninth and Fourteenth Amendments to the United States Constitution, the Developmental Disabilities Assistance and Bill of Rights Act, 42 U.S.C. § 6001 *et seq.*, and the National Research Act, Public Law No. 93-348, and its implementing regulations.

3. Jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1343(3)&(4) which provide for original jurisdiction for suits authorized by 42 U.S.C. § 1983.

4. Because this action arises under the Constitution and laws of the United States, jurisdiction also is conferred upon this Court by 28 U.S.C. § 1331.

5. Plaintiffs' request for declaratory relief is authorized by 28 U.S.C. §§ 2201–2202.

6. Additionally, this Court is requested to exercise its pendent jurisdiction over the state claims alleged herein which arise out of the same nucleus of operative fact as the federal claims.

VENUE

7. Venue lies in this judicial district pursuant to 29 U.S.C. § 1391(b).

PARTIES

8. The plaintiff is the estate of Mary Doris Diane LeClair who at the time of her death was an eighty pound, twenty-six year old blind and profoundly retarded ward of the State of Florida and its Department of Health and Rehabilitative Services (HRS). The estate is bringing this action by its personal representative, Alfred LeClair. Alfred and Stella LeClair also bring this action on their on behalf as Mary's parents.

9. The defendant, Dr. Harvey R. Langee, is a psychiatrist who at all times material to this complaint was employed by the State of Florida and HRS at the Gainesville Sunland Training Center. As part of his employment, Dr. Langee provided medical services to Mary. He is sued in both his individual and official capacity.

10. The defendant, Dr. Charles A. Williams, is the Medical Director of the Gainesville Sunland Training Center and was Medical Director at all times material to this complaint. As Medical Director, Dr. Williams is responsible for maintaining the standards of professional and ethical practice in the provision of medical and pharmacy services at the Gainesville Sunland Training Center, HRS Manual 160-6 at pp. 2-1, Attachment 1, p. 1 (1980), including those services provided to Mary. He is sued in his individual and official capacity.

11. The defendant, James L. Wilkins, Jr., is the Superintendent of the Gainesville Sunland Training Center and was Superintendent at all times material to this complaint. As Superintendent, he is responsible for the care, habilitation, treatment, training and protection of all persons confined at Gainesville Sunland, including Mary. He is sued in his individual and official capacity.

12. The defendant, Charles M. Kimber, is the Director of the Developmental Services Program Office of HRS, State of Florida, and was Director at all times material to this complaint. As Director, Mr. Kimber is responsible for all retardation and developmental disabilities programs operated by the Department pursuant to § 20.19, Fla. Stat. (Supp. 1980). Also as Director, Mr. Kimber was responsible for the development and oversight of programs affecting Mary. Further, pursuant to authority delegated to him by the Secretary of HRS, Mr. Kimber has the responsibility to assure compliance with HRS directives governing clinical trials and experimentation involving mentally retarded and other developmentally disabled HRS clients. He is sued in his individual and official capacity.

13. The defendant, David H. Pingree, was the Secretary of HRS at all times material to this complaint. As Secretary, he had overall responsibility for institutions and services provided to mentally retarded and other developmentally disabled citizens in the State of Florida, including Mary, pursuant to §§ 20.05, 20.19, Fla. Stat. (1979). As Secretary, Mr. Pingree also was responsible for the development and enforcement of rules and policies to protect Mary from harm as an institutional client. Further, Mr. Pingree had the specific responsibility to enforce HRS' general assurance issued to the U.S. Department of Health, Education and Welfare (now Health and Human Services) pursuant to the National Research Act and its implementing regulations, 45 C.F.R. Part 46 (1979), governing protection of human subjects involved in the institutional experimentation. Moreover, by his own directive, Mr. Pingree was obligated to review personally all clinical trials and experimentation involving HRS clients. He is sued in both his individual and official capacity.

14. The defendent, Alvin J. Taylor, succeeded Mr. Pingree as Secretary of HRS and was Secretary at the time the

original complaint in this action was filed. Mr. Taylor is sued only in his official capacity because he and his successors in our office are a necessary party defendant to the plaintiffs' request for declaratory relief.

15. The defendant, Lorraine Folkerts, is the director of pharmacy services at the Gainesville Sunland Training Center and was the director at all times material to this complaint. As director of pharmacy services, she is responsible for providing high quality pharmaceutical services to the residents of Gainesville Sunland and to insure that drug utilization standards are established and carried out correctly so as to satisfy all legal requirements, professional standards and HRS policies. HRS Manual 160-6, Attachment 1 (1980). She is sued in her individual and official capacity.

16. At all times relevant hereto, defendants Dr. Langee, Dr. Williams, Mr. Wilkins, Mr. Kimber, Mr. Pingree and Ms. Folkerts (hereafter called the individual defendants) acted under color of state law to deprive Mary of her rights, privileges and immunities under the Constitution and laws of the United States.

17. The defendant, State of Florida, was responsible for providing its ward, Mary LeClair, with a safe, humane and habilitative environment while she was confined at Sunland. The State of Florida also was obligated to observe the rights conferred upon Mary relating to State provided services which entail the administration of hazardous or experimental drugs, or uses of drugs which exceed standards established by the U.S. Food and Drug Administration. The State of Florida has waived its Eleventh Amendment immunity under the United States Constitution through the enactment of § 768.28, Fla. Stat. (Supp. 1980).

FACTUAL ALLEGATIONS

18. Mary LeClair was developmentally disabled as defined in 42 U.S.C. § 6001(7) and § 393.063(6), Fla. Stat. (1979). More specifically, she was profoundly retarded as a result of a birth injury and later in her life developed physical maladies including, among others, severe scoliosis and a combination of bilateral keratoconus and glaucoma which eventually caused her to become totally blind in 1975.

19. Simply defined, mental retardation is an impairment in intellectual functioning and adaptive behavior. All mentally retarded persons are capable of some development and learning and have the same feelings and humanity as other citizens.

20. In 1959, at the age of six, Mary was involuntarily committed by court order to the Gainesville Sunland Training Center, then called the Florida Farm Colony for the Epileptic and Feeble-Minded. This institution is owned and operated by the State of Florida. She resided at Gainesville Sunland until her death on February 15, 1979.

21. While at Gainesville Sunland, Mary resided in a series of cottages in which she was provided with custodial care. As a result of neglect, boredom and lack of stimulation in her barren and progressively darkening environment, Mary became withdrawn and began engaging in the repetitive stereotyped behaviors typical of persons subject to long-term institutionalization.

22. In particular, around 1973 Mary began exhibiting disruptive and self-abusive behavior manifested as frequent screaming, general upsets and occasional scratching. This behavior became more frequent just prior to and after the time she completely lost her vision in 1975. Mary's Gainesville Sunland caretakers attributed her behavior to the pain she was experiencing due to her eye condition.

23. Instead of responding with appropriate medical care and behavioral programming, Sunland staff initially endeavored to control Mary by administering major psychotropic medications to her on an ad hoc basis. Then, in May of 1975, Sunland personnel began regularly giving Mary mellaril, a major psychotropic drug. This drug, however, proved to be ineffective and was in fact contraindicated in Mary's case because she was then suffering from glaucoma.

24. In August of 1976, Mary was evaluated by defendant Dr. Langee. He noted the inappropriateness of her drug regimen and immediately substituted librium, a minor tranquilizer, for the mellaril she had been receiving for over a year. He also ordered stimulation therapy through music or some other mode at that time.

25. Defendant Dr. Langee continued to see Mary intermittently from August of 1976 until January of 1979. During that lengthy period, he maintained Mary on librium and reported substantial improvement in her general condition and a reduction in her disruptive and self-abusive behavior. Additionally, he reordered music therapy on two occasions. After his visit with Mary in May of 1978, for example, Dr. Langee specifically recommended music therapy during which Mary could control the music and hence not have as much time to sit by herself confused about what was going on around her. Sunland personnel, however, failed to provide any such therapy.

26. In or about October of 1978, defendant Dr. Langee instituted experimental lithium carbonate trials for a number of Gainesville Sunland residents. He did so with the approval of defendants Dr. Williams, Mr. Wilkins, and Ms. Folkerts, and on information and belief, with the approval or acquiescence of defendants Mr. Pingree and Mr. Kimber.

27. Ultimately, at least forty Gainesville Sunland residents were subjected to such experimental trials. Notably, no residents in the State of Florida's five other Sunlands were receiving lithium for any purpose at that time.

28. Lithium has been approved by the U.S. Food and Drug Administration for only two uses. These include the treatment of manic episodes in manic-depressive illness and maintenance therapy in those manic-depressive patients with a history of mania. The specific biochemical mechanism of lithium action in mania is unknown. Medical professionals, however, believe lithium may act to correct chemical imbalances in certain nerve impulse transmitters that influence emotional status and behavior.

29. Lithium is a hazardous drug. Its dangerousness stems from the fact it becomes toxic at close to therapeutic blood serum levels in most patients and can become toxic at normally therapeutic blood serum levels in others. Or in other words, lithium has a very narrow therapeutic index. Also, a myriad of mild to severe adverse side effects are associated with its use. As a consequence, lithium is subject to comprehensive safeguards well-known among medical and pharmaceutical professionals. These safeguards and the underlying reasons for them were well-known when the Gainesville Sunland lithium trials were commenced.

30. To insure safe usage, a patient's fitness for treatment with lithium must be determined before a trial is commenced. Once therapy is begun, a patient's serum lithium levels and clinical response must be monitored regularly. Frequent serum level checks during a patient's initial stabilization period and regular checks thereafter are required to make sure he or she is receiving the proper dosage. Continuous clinical evaluation is required to allow for the assessment of therapeutic value and the timely identification of adverse side effects and potentially life threatening

intoxication. Clinical evaluation is particularly important because toxicity can occur at normally safe serum levels in some individuals and because the severity of intoxication is related to both serum lithium level concentration and the duration of exposure to toxic levels. Hence, lithium intoxication must be diagnosed and treated as early as possible.

31. The use of lithium to treat behavior disorders in the mentally retarded has not been approved by the U.S. Food and Drug Administration (FDA) nor has it become a generally accepted practice among mental retardation and medical professionals. FDA approval and acceptance by practicing professionals must await the completion of a sufficient number of properly executed studies and trials which conclusively demonstrate lithium's effectiveness in the treatment of behavior disorders in the mentally retarded and its preferability over existing alternative treatments. Until such approval is obtained, lithium administration in this context constitutes an experimental and unapproved use.

32. On January 22, 1979, defendant Dr. Langee ordered a lithium trial for Mary LeClair because of her alleged behavior problems. He made no diagnosis of manic-depressive illness nor apparently did he consider one. Hence, his administration of lithium to Mary constituted an unapproved and experimental use.

33. At the time Mary's lithium trial was commenced, she was not exhibiting conduct which subjected herself or others to imminent physical harm. Indeed, none of defendant Dr. Langee's reports on Mary throughout the three and a half year period preceding the lithium trial contain any evidence of deterioration in Mary's condition which would explain why such a drastic course of treatment, an experimental lithium trial, was warranted. In fact, Mary's behavior problems had diminished according to her Sunland

records and Dr. Langee himself. Moreover, all less intrusive and potentially effective treatment alternatives, such as thrice requested but never implemented music therapy, had not been exhausted.

34. Additionally, there were obvious medical contraindications to lithium use in Mary's case. Most notably, she was under continuing treatment from Sunland's severe malnutrition clinic at the time of her trial. She weighed only 80 pounds (5'4" tall) at the time of her death.

35. Hence, Mary's lithium trial was both unnecessary and in fact was medically contraindicated. Less restrictive and less intrusive forms of appropriate treatment were available which would not have threatened her life.

36. Mary developed an array of symptoms of toxicity during the three-week period she received lithium. After severe symptoms appeared on February 13, 1979, she was taken first to the Gainesville Sunland hospital and then to the emergency room at Shands Teaching Hospital in Gainesville. Her serum lithium level on February 13, 1979, was over two times the level considered lethal. She died shortly thereafter on February 15, 1979. Her death was due to lithium intoxication according to the autopsy report.

37. The conduct of the individual defendants throughout the series of events leading to Mary's death was, as detailed below, willful and in gross disregard of Mary's fundamental rights guaranteed under state and federal law.

38. Because of the experimental nature of the lithium trials and the fact they involved the use of a hazardous drug, a research protocol was required under state and federal law. The individual defendants, however, failed to file or assure the filing of a research protocol establishing: (a) the potential risks and benefits for patient participants; (b) screening procedures for determining the suitability of

patients for the lithium trials; (c) procedures for obtaining express and informed consent from patients if competent or their parents or legal guardians if incompetent; (d) procedures for requiring direct care staff training in the monitoring of relevant behavioral and physiological manifestations of the patients' reactions to lithium; and (e) safeguards for the proper testing of serum lithium levels in the patients' blood. Further, these defendants failed to subject the protocol to professional peer and lay review to assure its appropriateness and safety for mentally retarded patients as required by state and federal law.

39. The individual defendants' failure to observe the above prerequisites contravened HRS' general assurance to the U.S. Department of Health, Education and Welfare (now named Health and Human Services) that HRS would abide by HEW regulations under the National Research Act, 45 C.F.R. Part 46 (1979), which protect human subjects involved in institutional experimentation supported by HEW funds. Gainesville Sunland received significant HEW funding for medical, habilitative and residential services which, on information and belief, defrayed some or all of the costs associated with the lithium trials.

40. The above prerequisites for a research protocol and professional peer and lay review also are mandated by the due process clause of the Fourteenth Amendment of the U.S. Constitution, *Wyatt v. Stickney,* 344 F.Supp. 387, 401-02 (M.D.Ala. 1972), and state statute and rules, § 20.19(7)(g)(3) and § 393.13(3)(f)(6), Fla. Stat. (1979); HRS Directive No. 15.01 (July 1972).

41. In the context of mentally retarded subjects, the need for a properly designed and approved protocol for lithium use is acute. Unlike most patients, profoundly retarded persons generally do not have the capacity to communicate to their physicians and caretakers the manner in which a

drug is affecting them. This is particularly a problem in non-verbal, profoundly retarded patients such as Mary LeClair. Consequently, direct care staff responsible for institutionalized retarded patients on lithium must be properly trained or relevant manifestations of their reactions will likely not be communicated to the prescribing physician.

42. In this case, Mary's fitness for lithium therapy was not determined prior to the initiation of her clinical trial. A cursory review of her records would have revealed that all less intrusive alternatives had not be exhausted. It also would have revealed the fact there were medical contraindications to lithium use in her case which called for further medical evaluation prior to the commencement of any trial. The individual defendants, however, failed to review or assure the review of Mary's records.

43. Additionally, the individual defendants failed to obtain informed consent for Mary's experimental trial from her or her parents. Mary, herself, was considered by HRS to be incompetent to give such consent. On information and belief, the individual defendants also failed to secure informed consent from the other subjects of the experimental lithium trials, or from their guardians if incompetent.

44. The individual defendants failed to train or assure the training of direct care staff to monitor Mary's and the other subjects' clinical responses to lithium. More particularly, staff were not informed about significant behaviors and side effects they should have recognized and reported nor were they instructed about the symptoms of lithium toxicity and how to respond to them.

45. This lack of training directly contributed to the events leading to Mary's death. Notably, Mary's behavior markedly changed immediately after lithium was administered to her. She became hyperactive and began to traumatize her head and body against various objects in the cottage

where she was confined. Her lithium dosage was subsequently erroneously increased, and she developed ever worsening signs of intoxication. Her early symptoms, e.g., protracted loss of appetite, were diagnosed as possible signs of a cold by uninformed Sunland medical staff. The staff did not even suspect Mary was suffering from intoxication until she was exhibiting symptoms of severe toxicity, namely flaccid muscles, incontinent urine and feces, seizures and coma. The lack of a prompt diagnosis and the excessive duration of Mary's exposure to toxic lithium levels played a contributory role in her demise.

46. Furthermore, the individual defendants failed to implement or assure the implementation of adequate procedures for monitoring blood serum levels of the trial subjects to insure they were receiving proper lithium dosages. Notably, a Tampa based laboratory was employed to test serum levels despite the existence of a number of adequate laboratories in Gainesville, including one at Gainesville Sunland. Timely and accurate laboratory reports are critical to the effective monitoring of serum lithium levels. The reliance on the out-of-town laboratory consequently compromised the integrity of the lithium testing since it required telephonic transmission of laboratory results prior to the delivery of more reliable written reports. In Mary's case, the telephonic transmission of her laboratory results led to an error which caused her lithium dosage to be increased under defendant Dr. Langee's standing drug order at a time when she was already in a toxic state.

47. Moreover, the consequences of the increased dosage resulting from the misreported laboratory results may have been further aggravated by the failure of defendants Dr. Langee and Ms. Folkerts to assure the issuance of a discontinue order on Mary's original prescription. On information and belief, the failure to issue a discontinue order resulted in Mary's receiving lithium dosages on both the

original prescription and the revised one under the standing order.

48. In addition to their personal involvement in the Gainesville Sunland lithium trials, defendants Mr. Pingree and Mr. Kimber knew of the existence of serious, general problems associated with the administration of psychotropic drugs in HRS facilities before the lithium trials were instituted. Despite this knowledge, these defendants failed to perform their duty to promulgate and enforce procedures and policies which would have remedied those acknowledged problems. By this failure to properly supervise, combined with their acquiescence in their subordinates' conduct and their own acts and omissions, defendants Pingree and Kimber deprived Mary of her rights.

49. The acts and omissions of defendants Pingree, Kimber, Wilkins, Williams and Folkerts, as highranking state officials, constitute the policies, practices and customs of the defendant State of Florida.

50. The acts and omissions of all of the individual defendants were willful and in gross disregard of the rights of Mary LeClair. Further, these defendants were deliberately indifferent to her serious medical needs.

ADMINISTRATIVE EXHAUSTION

51. There are no adequate and appropriate administrative remedies under Florida law for plaintiffs' claims under 42 U.S.C. § 1983 within the meaning of *Patsy v. Florida Int'l Univ.*, 634 F.2d 900 (5th Cir. 1981).

52. The *Patsy* decision was rendered after plaintiffs' causes of action had accrued. To apply its holding retroactively would result in manifest injustice to the plaintiffs.

53. To the extent the notice procedure of § 768.28(6), Fla. Stat. (Supp. 1980), may apply, the plaintiffs complied by giving notice of their claim in writing to HRS. HRS thereafter gave the Florida Department of Insurance actual notice of the claim, and the Department investigated it. Neither HRS or the Department made a final disposition of the claim, and this action was filed more than six months after notice was given.

54. The notice procedure of § 768.28(6) need not be exhausted because it does not apply to claims based on the bad faith or wanton misconduct of the State's agents and employees, as are alleged herein. *Bisschop v. Harris,* No. 79,454-Orl-Civ-R (M.D. Fla., order filed May 19, 1981).

55. The defendants have waived the notice requirements of § 768.28(6) and are estopped from asserting them against the plaintiffs.

CLAIMS FOR RELIEF

56. Because lithium was prescribed without informed consent, intrusively, inappropriately, and in lieu of less restrictive habilitation, Mary LeClair's rights to appropriate treatment, services and habilitation, as guaranteed by the Fourteenth Amendment to the United States Constitution, 42 U.S.C. § 6010 and 42 U.S.C. § 1983, were violated.

57. By subjecting Mary LeClair to dangerous conditions without adequate safeguards in the lithium experiment which caused her death, the defendants violated Mary's right to be protected from harm, as guaranteed by the Eighth and Fourteenth Amendments to the United States Constitution, 42 U.S.C. § 6010, 42 U.S.C. § 1983, and the National Research Act and its implementing regulations.

58. By subjecting Mary LeClair to an intrusive drug regimen, the defendants violated her right to privacy and bodily integrity, as guaranteed by the First, Ninth and Fourteenth Amendments to the United States Constitution and 42 U.S.C. § 1983.

59. By subjecting Mary LeClair to an experimental drug regimen without a habilitative purpose and under dangerous conditions which proved to be lethal, the defendants violated her rights under § 393.13, Fla. Stat. (1979).

60. Defendant Dr. Harvey R. Langee acted negligently and breached his duty to Mary LeClair to provide her with a professionally acceptable standard of care.

61. The plaintiffs Alfred and Stella LeClair have lost their daughter because of the violations committed by the defendants and hence claim damages to compensate them for the mental and emotional distress and suffering caused thereby.

PRAYER FOR RELIEF

In light of the foregoing, the plaintiffs respectfully pray this Court to grant the following relief:

1. Compensatory and punitive damages against all the defendants jointly and severally;

2. A declaration that the defendants have violated the written assurances provided in Florida's Developmental Disabilities State Plan which mandate the provision of appropriate treatment, services and habilitation and which prohibit the use of excessive chemical restraints as a substitute for appropriate habilitation;

3. A declaration that the defendants have violated Florida's general assurance under the National Research Act and HEW regulations;

4. A declaration that, with respect to institutional utilization of hazardous or experimental drugs, the right of patients or their guardians if incompetent to informed consent is absolute under the Fourteenth Amendment;

5. All costs in this action, including a reasonable attorneys' fee as provided by 42 U.S.C. § 1988;

6. Any and all such other relief as justice and equity require.

DEMAND FOR JURY TRIAL

The plaintiffs respectfully demand trial by jury.

Respectfully submitted,

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By /S/ Albert J. Hadeed
Attorneys for Plaintiffs

APPENDIX D

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
GAINESVILLE DIVISION

ESTATE OF MARY DORIS DIANE LECLAIR, et al.,
Plaintiffs,
v. Case No. GCA-81-0008

DR. HARVEY R. LANGEE,
et al.,
Defendants.
_____/

SETTLEMENT AGREEMENT

The plaintiffs, Estate of Mary Doris Diane LeClair, and Alfred and Stella LeClair, and the defendants, David H. Pingree, Charles M. Kimber, James L. Wilkins, Jr., Charles A. Williams, Lorraine Folkerts, and their successors in office (hereafter collectively referred to as "HRS defendants") hereby stipulate and agree as follows:

WHEREAS this action was instituted by the plaintiffs on February 13, 1981, alleging violations of the United States and Florida Constitutions, the Federal Civil Rights Act (42 U.S.C § 1983), the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. § 6001 *et seq.*), the National Research Act (Public Law 93-348), and the Florida Bill of Rights of Retarded Persons (§ 393.13, Fla. Stat. (1981)), based on the alleged maladministration of psychotropic drugs;

WHEREAS the complaint, as amended, sought compensatory and punitive damages, and injunctive and declaratory relief;

WHEREAS the HRS defendants have denied liability;

WHEREAS the plaintiffs' primary interest in initiating this action is for the HRS defendants to establish an appropriate and adequate system for administering psychotropic medications safely and therapeutically in HRS institutions;

WHEREAS on May 15, 1981, the HRS defendants promulgated an internal regulation numbered 95-3 governing the administration of psychotropic medications in HRS institutions;

WHEREAS the plaintiffs have analyzed the HRS regulation and identified certain areas for revision;

WHEREAS the HRS defendants agree to make the revisions;

WHEREAS plaintiffs have agreed to waive their claims for punitive damages in return for the adoption and incorporation of their revisions;

WHEREAS the parties wish to amicably resolve their differences without the necessity and expense of protracted litigation.

WHEREAS the parties are entering into this agreement to resolve and finally settle all disputes and controversies between them arising out of the claims asserted by the plaintiffs;

WHEREAS the signatories to this agreement represent they are authorized to enter into this agreement and to take all steps required of them by this agreement;

NOW THEREFORE, the parties hereby stipulate to the following:

A. The HRS defendants shall pay to the plaintiffs within 10 days of the Court's Order approving and adopting this settlement agreement the sum of Seven Thousand Five Hundred (7,500) Dollars as and for compensatory damages.

B. The plaintiffs hereby waive any and all claims to punitive damages.

C. Attached hereto and incorporated by reference as Exhibit A is the HRS regulation governing administration of psychotropic medications in HRS institutions as it presently exists. After this Court approves and adopts this settlement agreement, the HRS defendants shall implement the attached HRS regulation according to the revisions specified in Exhibit B which is attached hereto and incorporated by reference.

D. Promptly upon execution of this agreement, counsel for the parties shall jointly submit this agreement to the Court for its approval and recommend the Court approve the agreement. This agreement shall be effective immediately upon entry of the proposed order attached as Exhibit C. Neither party will appeal the order approving this agreement.

E. Plaintiffs' counsel, after negotiating the compensatory damages award specified in Section A above, agreed to compromise his claim for attorneys' fees and expenses as an inducement to obtaining the agreement of the HRS defendants to regulatory reform. The parties agree that plaintiffs' counsel shall receive the sum of Five Thousand ($5,000) Dollars within 10 days of the Court's order approving this agreement in full satisfaction of any and all claims under 42 U.S.C. § 1988.

F. The parties agree that for a period of nine months after Court approval of this agreement, the Court shall retain

continuing jurisdiction to enforce or modify this agreement on motion of any of the parties.

G. This agreement and its exhibits contain the entire agreement between the parties.

For the plaintiffs
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By: /s/
Albert J. Hadeed

@LINE = Dated:

For the HRS defendants
CLAIRE DRYFUSS
Assistant General Counsel
Department of Health and
Rehabilitative Services
1323 Winewood Boulevard

By: /s/
Claire Dryfuss

Dated:

HRSR 95-3

STATE OF FLORIDA
DEPARTMENT OF HEALTH
AND REHABILITATIVE SERVICES
TALLAHASSEE, May 15, 1981

HRS REGULATION
NO. 95-3

Institution Management

PSYCHOTROPIC DRUG REGULATIONS FOR HRS INSTITUTIONS/RESIDENTIAL FACILITIES

1. Purpose. This regulation provides the guidelines for the use of psychotropic drugs for patients in institutional and residential facilities of the Department of Health and Rehabilitative Services.

2. Scope. This regulation is established for the benefit of all patients of HRS who will be receiving psychotropic drugs in HRS institutions and residential facilities. A period of training on these regulations for all direct care staff will help to ensure additional checks and balances to patients receiving such drugs.

3. References.

a. Section 20.19, Florida Statutes

b. Chapter 393, 394, 396, 397, 458, 459, 460, 465, and 893, Florida Statutes

c. HRSR 120, (HRS Regulation)

d. HRSM 130-3, 160-2, and 160-5, (HRS Manuals)

OPIR: OPIRM
DISTRIBUTION: X: OSES(1), OSIG(3), OSLP(1), OSLS(1), OSPI(1), ASA(1), ASGA(10), ASRMA(1), ASP(1), PDDPP(1), PDDHD(1), PDAA(1), PDCM(1), PDDS(3), PDHE(20), PDMH(7), PDVR(1), PDCYF(4), ASO(1), OPCM(1),

OPIR(1), OPIRM(50), OPLC(6), HRS Resource Center(3), Auditor General(13).

DISTRICTS DISTRIBUTE AS FOLLOWS:

DISTRICT NUMBER	1	2	3	4	5	6	7	8	9	10	11	TOTAL
DA	1	1	1	1	1	1	1	1	1	1	1	11
DASD	1	1	1	1	1	1	1	1	1	1	1	11
DPM	1	1	1	1	1	1	1	1	1	1	1	11
DPOAA	1	1	1	1	1	1	1	1	1	1	1	11
DPODS	1	1	1	1	1	1	1	1	1	1	1	11
DPOMH	1	1	1	1	1	1	1	1	1	1	1	11
DPOCYF	1	1	1	1	1	1	1	1	1	1	1	11
DPOVR	1	1	1	1	1	1	1	1	1	1	1	11
CHU'S	4	14	16	7	2	2	4	10	5	1	2	67
To DPOHE for Distribution to Appropriate Institutions and Facilities	6	18	15	9	3	12	12	18	12	6	9	120
TOTAL	18	40	39	24	13	22	24	36	25	15	19	275

EXHIBIT A

4. Definitions.

a. Attending Staff Physician. An HRS licensed staff physician is responsible for initiating and following all medical care of individual patients. Upon receiving consultation data and recommendations, the attending physician shall assess all factors involved and order all treatments. This physician has the responsibility of modifying, stopping, or changing the drugs based on the patient's condition, laboratory tests, and review assessments. The attending staff physician shall refer patients to physician consultants. Nothing in these guidelines shall be construed to prevent the attending staff physician of the institution/residential facility from prescribing psychotropic drugs or approving the use of these for a patient in a manner consistent with provisions provided for by the P&T committee so long as the basis for clinical judgment to do so is recorded in the patient's medical record.

b. Clinical Pharmacist. A consultant pharmacist who has either completed:

(1) An approved clinical residency or Doctor of Pharmacy (Pharm. D.) program and is approved by the Director of Pharmacy and the Pharmacy and Therapeutic (P&T) Committee.

(2) Two years of service in the institution with an "above satisfactory" or higher evaluation and during this period has been involved in clinical practice that has been approved by the Director of Pharmacy.

c. Consultant Pharmacist. A Florida licensed pharmacist who has submitted to the Florida Board of Pharmacy proof satisfactory that he has the requirements to be a consultant pharmacist through one of the following:

(1) The pharmacist holds a Master of Science degree in hospital pharmacy.

(2) the pharmacist has completed an American Society of Hospital Pharmacy (ASHP) residency in hospital pharmacy or its equivalent.

(3) The pharmacist has attended either:

(a) an annual Consultant Pharmacist Conference sponsored by the College of Pharmacy, University of Florida, or the School of Pharmacy, Florida A&M University;

(b) an American Society of Hospital Pharmacists Institute on the general practice of hospital pharmacy within the previous three year period.

(4) Upon acceptance of the above proof, the Florida Board of Pharmacy will license the pharmacist as a consultant.

d. Contract Physician. A physician in private practice under contract with the Department of Health and Rehabilitative

Services. These physicians shall follow these psychotropic guidelines and other HRS regulations while attending HRS clients. They shall not conduct any experimentations without filing the appropriate research protocols as described in the HRS Drug Formulary.

e. Direct Care (Hands on Care). Direct day-to-day personal services to clients providing for their activities of daily living, physical care, comport, prevention of illness, and maintenance of health and safety.

f. Direct Care Staff. The institution/residential facility personnel who are not licensed by the State of Florida but have hands on care responsibilities for the patients.

g. Habilitation. Means the process by which a client is assisted to acquire and maintain those life skills which enables him to cope more effectively with the demands of his condition and environment and to raise the level of his physical, mental, and social capabilities. It includes, but is not limited to, programs of formally structured education and habilitation therapies.

h. Licensed Professional Nurse (R.N.). Those individuals who have met the minimum requirements for safe practice of nursing in the State of Florida and are duly licensed by the State. The practice of professional nursing means the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skills based upon applied principles of psychological, biological, physical, and social sciences.

i. Medical Consultations. A deliberation by two or more physicians about diagnosis or treatment in a particular case. The consultation is limited to those services rendered by a physician in the evaluation and/or treatment of a patient's mental illness, behavior disorders, or physical problems.

j. Pharmacy and Therapeutic (P&T) Committee. The P&T Committee shall have the responsibility for planning, reviewing, and controlling the psychotropic drug program in each of the institutions or residential facilities. Membership on this committee will include, but is not limited to, the following:

(1) Florida licensed physicians, dentists, nurses, and consultant pharmacists.

(2) Hospital Administrator or his designee from the Hospital management staff.

(3) Allied health care professionals as appropriate.

(4) In addition to listed members of the committee, there must be contributions from non-licensed direct care staff for all patients being reviewed who are being treated with psychotropic drugs.

k. Psychotropic Drug. One which exercises a direct effect on the central nervous system and which is capable of influencing and modifying behavior. Drugs included in this guideline are as follows:

(1) Antipsychotics, such as chlorpromazine;

(2) Antidepressants, such as imipramine;

(3) Antianxiety agents, such as diazepam;

(4) Agents which control behavior, such as lithium;

(5) Sedatives and hypnotics, such as chloral hydrate and flurazepam, and

(6) Psychomotor stimulants, such as methylphenidate.

l. Psychiatric Consultant. A physician with a minimum of three years of residency training in psychiatry who is board eligible or board certified.

m. Treatment. Prevention, improvement, and curative measures taken to relieve patients of both physical and mental illnesses, behavior disorders, diseases, and disabilities.

5. Utilization of Psychotropic Drugs.

a. Psychotropic drugs should be used for control or modification of behavior of patients only when necessary as part of the plan for treatment of the patient and not as the most favored means of suppressing undesirable behavior or modifying behavior.

b. Psychotropic drugs should not be used as punishment, as a substitute for behavioral programs, for staff convenience, or in dosages which interfere with the habilitation/treatment plan for the patient.

c. There shall be no standing orders for psychotropic drugs.

d. Psychotropic drugs must be used under the direction of a Florida licensed physician when the physician has prescribed the drug for the purpose(s) which the physician has described in the patient's chart.

e. Adequate initial dosages should be used to obtain desired results, and therefore, the initial dosage has to be cautiously and individually determined. For elderly or debilitated patients or those patients who have reported high sensitivity to drugs in the past, special surveillance shall be required.

f. Periods of administration of large doses shall not initially exceed either one week, or the essential time needed to relieve critical symptoms, whichever is less.

g. Psychotropic drugs shall be reordered at specified time periods on the basis of the patient's responses and needs. Periods of drug orders should be mandated by the P&T Committee in their written institution/residential facility policy.

h. As soon as the patient's condition is deemed stabilized, efforts shall be made to gradually reduce drug dosages to a minimum when drugs are required to be continued for an extended period of time.

i. Drug holidays shall be established, when possible, as part of the drug dosage schedule. In the use of antipsychotic and antidepressant drugs, a drug-free day each week, or a drug-free weekend, or an every-other-day dosage, etc., shall be considered for patients and documented in the medical record.

j. Antianxiety drugs shall be used only for anxiety which markedly interferes with the patient's performance, or for anxiety which results in unmanageable behavior. The continual use of drugs for anxiety is not believed justified since the effectiveness of antianxiety agents has been determined to be rather short lived. Prolonged use may increase drug dependence or tolerance.

k. Written procedures shall be established to cover dosages and uses of psychotropic drugs in accordance with usual institution/residential facility and clinical practices to include written reviews and written medical rationale for varying dosages. When dosage levels are ordered in excess of the maximum listed in the following table they must be justified and documented in the medical record prior to initiating therapy, approved by the medical or clinical director, and reviewed by the P&T Committee at frequent intervals. The P&T Committee actions on drug reviews that are not within the confines of usual psychotropic drug use according to the MADPD chart shall be sent through the medical or clinical director to Medical Services and Basic Care (QPIRM) for review and comments.

THE MAXIMUM ALLOWABLE DAILY PSYCHOTROPIC DOSAGE CHART (MADPD)

Drug (oral mg)	Milligrams (mg Necessary Relative to 100 mg of Thorazine[a]	Maximum Per Day Allowable Milligrams
Choropromazine (Thorazine)	100	2001 – 2500
Thioridazine (Mellaril)	100	901 – 1000
Mesoridazine (Serentil)	50	501 – 600
Prochlorperazine (Compazine)	15	50[b]
Perphenazine (Trilifon)	10	65 – 86
Trifluoperazine (Stelazine)	5	61 – 70
Fluphenazine (Prolixin)C255	2	61 – 80
Thiothixene (Navane)	5	101 – 120
Haloperidol (Haldol)	2	81 – 100
Loxapine (Loxitane)	10	141 – 160
Lithium (Lithonate, Lithium Citrate)	–	1,800[c]
Molindone (Moban)	10	176 – 600
Hydroxyzine (Vistaril)	–	501 – 600
Doxepin (Sinequan)	–	361 – 400
Diazepam (Valium)	–	81 – 100

[a]The relative Thorazine potency figures are for reference as compared to what 100mg of Thorazine would represent, i.e., 2mg of Haloperidol equals 100mg of Thorazine.

References: Drug Treatment, Avery (Hollister); Principles and Practices of Clinical Pharmacology and Therapy; Facts & Comparisons; Drug Information-1979; AMA Drug Eval. (3rd Edition); Modern Drug Encyclopedia & Therapeutic Index.

[b]For adults only.

[c]1,800 mg for short term usage and 1,200 mg for long term usage.

l. Procedures for emergency use of psychotropic drugs shall be developed for each institutional/residential facility by the P&T Committee.

m. Policies and procedures shall be developed and implemented in each institution/residential facility by the respective P&T Committees to handle the following situations. Usually, only one psychotropic drug is recommended to be used at a time, however, there are combinations which may be indicated which include the following:

(1) Antianxiety drugs with antidepressant drugs.

(2) Antiparkinsonian drugs should not be used routinely with psychotropic drugs unless indicated by the presence of parkinsonian side effects.

(3) If a dose(s) of a drug is followed by untoward symptoms then the drug may be discontinued, decreased in amount, or accompanied by other drugs so the dose of each drug can be lowered.

(4) When three or more psychotropic drugs are prescribed, the need must be documented in the patient's medical record, approved by the institution/residential facilities medical or clinical director, and reviewed by the P&T Committee at specified intervals.

n. Written informed consent for the use of psychotropic drugs shall be secured from patients, parents, guardians, or legal representative and placed in the active medical record when the patient is admitted to the institution/residential facility.

o. An institution/residential facility policy shall be established for the use of psychotropic drugs in children.

p. Directives. Whenever special directives are promulgated concerning psychotropic drugs, they will be appended to these guidelines. These directives will be for special

conditions which relate to unusual or unique situations in prescribing psychotropic drugs. A special directive is as follows:

(1) Lithium Directive. Under the direct supervision of a psychiatrist, the patient shall have documented a current physical examination, updated medical history, and laboratory assessment. Use of lithium requires quarterly review by the P&T Committee and the following:

(a) An initial assessment of thyroid, cardiac, and renal functions shall be done and noted in the patient's chart and shall be repeated according to institution/residential facility protocol.

(b) Serum lithium levels and sodium chloride blood levels.

1. Initially, lithium blood levels shall be determined at 24 hours.

2. No less often than every four days until the patient is stabilized.

3. Then weekly for one month.

4. Then monthly.

(c) The complete physical examination and laboratory tests shall be repeated according to the protocol.

(d) Nursing assessment plan and follow-up shall be completed and documented on the medical record. Licensed nurses shall closely supervise all patients requiring lithium treatment until the patient is stabilized on the drug.

(e) Documentation in the form of progress notes and shift-to-shift logs must be done at designated intervals by all attending Staff members according to the P&T Committee protocol.

(f) A written protocol shall be developed by the P&T Committee and reviewed annually.

6. Medical Services.

a. Physicians. The medical care of the patient is the responsibility of the attending physician. The coordination of special medical therapy plans from all sources (allied health, consultants, etc.,) is the responsibility of the attending physician.

(1) The physician on admission of the patient to the institution/residential facility should explain to the patient, parents, or guardians the application of psychotropic drugs in the patient's treatment, and explain that these drugs may be used to control or modify irregular behavior when necessary.

(2) When prescribing psychotropic drugs, the attending staff physician must diagnose the patient's problem(s) and document the symptoms and behavioral problems to be treated. This documented information will constitute the basis for which prescribing decisions will be made if psychotropic drugs are to be used.

(3) The attending staff physician initially prescribing psychotropic drugs must review the patient at frequent intervals to assure relief of untoward symptoms and side effects according to policies and procedures established by the P&T Committee.

(4) The patient's attending staff physician shall transfer and sign on the physician's order sheet all drugs recommended by any consultant which the attending staff physician deems appropriate before the pharmacist accepts the orders and treatment is started.

(5) Psychotropic drug therapy and progress of the patient shall be reviewed and documented by the attending

staff physician at a minimum of every thirty-one (31) calendar days.

b. Nursing Services. It is the responsibility of the licensed professional nursing staff to ensure that all appropriate documentation relating to administration of psychotropic drugs is recorded and that the required records for review by the P&T Committee are completed at required intervals. Also, it is the responsibility of the licensed professional nursing staff to provide supervision over direct care staff when they are performing nursing functions legally delegated (i.e., drug administration, patient observation, documentation of patient activities) and shall participate in direct care staff training in order that direct care staff can effectively function in providing these services to the patient who is on psychotropic drugs.

(1) Drug Administration. Drug administration is performed by licensed personnel (R.N.s and L.P.N.s).

(a) Non Unit Dose Drugs. These drugs are administered only by persons who are fully qualified.

(b) Injections. Only Licensed Professional Nurses (R.N.s) or Licensed Practical Nurses (L.P.N.s) under the direction of a R.N. should administer injectable drugs. Injectables will include Subcutaneous, Intra-muscular, and Intradermal.

(c) Intravenous. Intravenous drugs are administered only by a Registered Nurse or Physician.

(2) Drug Administration. By non-licensed personnel.

(a) Unit Dose Drugs. Non-licensed personnel who have successfully completed the established HRS Drug Administration Course may administer oral solid and liquid individual packaged unit-dose drugs, but must be

supervised by licensed professional nursing personnel or a licensed physician.

(b) Injectables. Injectable drugs shall not be administered by non-licensed personnel.

(c) Verbal Orders. Only the licensed professional nurse or licensed pharmacist may accept and record verbal orders for psychotropic drugs from licensed physicians.

(3) Observation.

(a) Licensed professional nurses shall monitor patients receiving psychotropic drugs for any unusual or unexpected reactions or behavior to the drugs and shall report any unusual reactions to the attending physician.

(b) Non-licensed personnel shall observe patients receiving psychotropic drugs for unusual or unexpected reactions or behavior and report to the nursing supervisor immediately any unusual or unexpected reaction or behavior. These employees acting within the scope of their employment have protection under the risk management fund for this responsibility.

(4) Documentation.

(a) Licensed professional nursing personnel must document patient behavior in such a way as to provide specific measurement of the behavior and frequence of behavior in order to provide baseline documentation for treatment. Licensed professional nursing personnel must supervise data recorded by non-licensed personnel.

(b) Licensed non-medical or direct care personnel must accurately record patient's observable actions. The data recorded must describe the patient's behavior and how the patient tolerates the drug. Follow-up notes on the effects of the psychotropic drug must be written at frequent intervals as established by the P&T Committee. Licensed

non-medical or direct care personnel must immediately report unusual or unexpected reactions or behavior to the appropriate licensed professional nursing supervisor.

(5) Communication.

(a) Licensed nursing professional personnel must communicate to non-licensed personnel the rationale for placing the patient on psychotropic drugs and what behavior is expected.

(b) Licensed non-medical or non-licensed personnel must report unexpected behavior to licensed nursing personnel.

c. Pharmacy Services. The Director of Pharmacy has the authority to delegate responsibilities to the clinical pharmacist and all duties of the clinical pharmacist have to be approved by the P&T Committee. The Director of Pharmacy will be responsible to supply contract and consultant physicians with a formulary of psychotropic drugs available for use in the institution/residential facility.

(1) The pharmacist's role in utilizing psychotropic drugs in HRS institution/residential facilities is a consulting role to the other professional staff members to optimize the drug benefits and minimize their side effects. The pharmacist will monitor the use of these drugs, dispense the drug, and provide a variety of pharmaceutical services such as drug information programs.

(2) A clinical or consultant pharmacist shall be a member of all committees which are directly involved with decisions concerning the use of psychotropic drugs. Their duties shall include:

(a) The pharmacist shall provide the P&T Committee with:

1. A comprehensive drug history on each patient to be placed on psychotropic drugs when possible.

2. Evaluations and recommendations of present drug therapy.

3. Drug information on alternative drugs.

4. Results of blood levels and other indicated laboratory tests pertaining to psychotropic drugs.

(b) Monitoring and assisting in the enforcement of corrective measures regarding the incident reporting system concerning the administration of psychotropic drugs in each institution and residential facility.

(c) The clinical or consultant pharmacist shall prepare a report to the P&T Committee monthly to include:

1. Number of clients on psychotropic drugs.

2. Names of psychotropic drugs with maximum doses prescribed.

3. List of patients receiving multiple psychotropic drugs who have been on the therapy for a period exceeding 31 days.

d. Pharmacy and Therapeutics Committee (P&T Committee) duties will be, but are not limited to, the following:

(1) Advisory to medical, pharmacy, and nursing staff on matters relevant to selection, purchasing, storage, distribution, use, safety, and other drug related activities.

(2) Developing procedures and policies for:

(a) Periodic review of patient placed on psychotropic drug treatments.

(b) Use of psychotropic drugs in greater dosages than those listed in the MADPD Chart (5. k.).

(c) Surveillance of psychotropic drug utilization.

(d) Documentation of observations from direct care staff serving those patients receiving psychotropic drugs.

(e) Patient drug information sheets will be provided to the patient, parents, or guardians when the patient goes on leave of absence from the institution/residential facility. The sheet will include the patient's name, the name of the drugs the attending physician has prescribed, the attending physician's name, the institution/residential facilities name and phone number, and any information relative to medical treatment of the patient while away from the institution/residential facility. The delivery of this sheet to the patient, parents, or guardians shall be documented in the patient's medical records.

e. Medical Records need to be accurate and complete to promote effective communication among the staff. The need is much greater when the patient is placed on psychotropic drugs. Information concerning patient treatment for medical and behavioral disorders needs to be extensively noted by all direct care staff so that the attending staff physician will be able to view the total treatment of the patient. Adequate documentation of staff observations in the record will allow the attending staff physician to measure the effect of the prescribed psychotropic drugs on specific symptoms or behavioral disorders being treated. The following are to be permanently included in the medical record of each patient:

(1) A complete medical history and physical examination on each patient must be in the patient's medical record.

(2) A comprehensive drug history shall be obtained and should include the use of other drugs, drug allergies, drug reactions, food allergies, and other allergic reactions.

(3) Habilitation and treatment plans must include the goals for the individual patient which are being set by each health professional and the allied health professional. Each professional therapy representative must state their objectives for the patient concerning the use of psychotropic drugs. The habilitation and treatment plans must include the specific symptoms and behavioral disorders to be treated. The habilitation and treatment plans shall be documented and retained in the medical record. The drug therapy recommendation including the kind and amount of drug must be documented in the patient's medical record before initiation of drug treatment.

(4) Effects on the specific symptoms and behavioral problems being treated as well as the actual effects of the drug shall have written documentation in the patient's medical record.

(a) The physician shall document the effects of the drugs prescribed in the progress notes for the specific symptoms and behavioral problems. The documentation should include the reason for decreasing, increasing, or stabilizing the patient after initiating drug therapy. The effects or overall therapy in relation to the patient's habilitation plan should be included.

@ONEABODY = (b) Licensed professional nurses shall document their observations of the effects of drug therapy on specific symptoms and/or behavioral problems in such a manner to provide a basis for further drug therapy decisions. Licensed professional nurses must supervise the notes placed in the patient's medical record by non-licensed direct care staff.

(c) The direct care staff shall routinely document the frequency of symptoms or behavioral disorders over the entire period of therapy, the degree of tolerance to the medication, unusual effects of symptoms they did not

observe before the initiation of drug therapy. The direct care staff must coordinate their observations under supervision of the licensed professional nursing personnel. The licensed professional nurse shall be responsible for making the recorded observations available to the P&T Committee.

(d) Licensed non-medical and allied health professional should document in the patient's medical record, if any, of the psychotropic drugs on their various therapy plans during the course of drug treatment. Comments should be included in the Habilitation and Treatment Plan, as well as the medical record.

(e) The dentist will determine drugs to be used for specific dental problems. The use of premedication should not conflict with the psychotropic drug treatment. If behavioral problems need to be treated, the dentist shall consult with the patient's attending staff physician. In emergency situations, the dentist may consult with the staff physician on duty.

(f) The clinical or consultant pharmacist shall document in the patient's medical record any laboratory drug analysis findings, evaluation of drug therapy from a pharmacological approach, and possible drug interactions of drugs being given.

BY DIRECTION OF THE SECRETARY:

OFFICIAL

RICHARD E. GRIMM
Assistant Secretary
for Operations